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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,173

05/15/2007

Tracy Gentry

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7590

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ALSTON & BIRD LLP

BANK OF AMERICA PLAZA

101 SOUTH TRYON STREET, SUITE 4000

CHARLOTTE, NC 28280-4000

EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

03/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,173	Applicant(s) GENTRY ET AL.	
	Examiner Michail A. Belyavskyi	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,6,8-15,54-57,59 and 61-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>05/19/07; 09/19/07;02/05/10</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1-3, 5, 6, 8 -21, 22,24-29, 31, 33-36,38, 40-43,45,47-50,52,54-57,59,61-75, 77,79-86, 88, 90- 95, 97, 99-104, 106, 108-113, 115, 117-120 .

Continuation of Disposition of Claims: Claims withdrawn from consideration are 16-21, 22, 24-29, 31, 33-36,38, 40-43,45,47-50, 52, 69-75, 77, 79-86, 88, 90- 95, 97, 99-104, 106, 108-113, 115, 117-120 .

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DETAILED ACTION

1. Claims 1-3, 5, 6, 8 -21, 22,24-29, 31, 33-36,38, 40-43,45,47-50,52,54-57,59,61-75, 77,79-86, 88, 90- 95, 97, 99-104, 106, 108-113, 115, 117-120 are pending.

2. Applicant's election without traverse CD45 as a specific cell surface marker is acknowledged.

3. Claims 16-21, 22, 24-29, 31, 33-36,38, 40-43,45,47-50, 52, 69-75, 77, 79-86, 88, 90- 95, 97, 99-104, 106, 108-113, 115, 117-120 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 1-3, 5, 6, 8-15, 54-57, 59, 61-68 read on a cell population of ALDH^{br} stem cells, wherein at least 10 % of the cell express at least CD105 are under consideration in the instant application.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5 Claim 1-3, 5, 6, 8-15, 54-57, 59, 61-68 are rejected under 35 U.S.C. 102(a) as being anticipated by Fallon et al (IDS) or Hess et al (IDS) .

Fallon et al., teach an isolated cell population of ALDH^{br} SSC^{lo} stem cells.(see entire document, Abstract in particular). Fallon et al., teach that said cells are CD34⁺ and CD45⁺ cells (see page 103 in particular). Although the reference is silent about that said population of ALDH

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^{br} SSC^{lo} stem cells comprises at least 10% of CD105⁺ cells, said structural properties would be an inherent properties of the referenced cell composition. Since the office does not have a laboratory to test the reference cell composition, it is applicant's burden to show that the reference cell composition does not comprises at least 10% of CD105⁺ cells as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Hess et al., teach an isolated cell population of ALDH^{br} SSC^{lo} stem cells that are CD34⁺ and CD45⁺ cells (see entire document, Abstract in particular). Although the reference is silent about that said population of ALDH^{br} SSC^{lo} stem cells comprises at least 10% of CD105⁺ cells, said structural properties would be an inherent properties of the referenced cell composition. Since the office does not have a laboratory to test the reference cell composition, it is applicant's burden to show that the reference cell composition does not comprises at least 10% of CD105⁺ cells as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Once a *prima facie* case of anticipation with a basis in fact and/or technical reasoning which reasonably supports the determination that an allegedly inherent characteristic necessarily flows from the teachings of the applied prior art is established it is applicant's burden to prove that the subject matter shown to be in the prior art does not possess the characteristics of the claimed invention. See *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Patent App. & Int. 1990); *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986) and MPEP § 2112.

Claims 8-15 and 61-68 are included because a composition is a composition irrespective of its intended use in the absence of evidence of structural difference. If the prior art structure is capable of performing the intended use, then it meets the claim. When a claim recites using an old composition or structure (e.g. ALDH^{br} SSC^{lo} stem cells) and the use is directed to a result or property of that composition or structure then the claim is anticipated. See MPEP 2112.02. Also, see *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.* 58 USPQ2d 1508 (CA FC 2001); *Ex parte Novitski* 26 USPQ 1389 (BPAI 1993); *Mehl/Biophile International Corp. V. Milgraum*, 52 USPQ2d 1303 (Fed. Cir. 1999); *Atlas Powder Co. V. IRECO*, 51 USPQ2d 1943 (Fed. Cir. 1999).

The references teaching anticipates the claimed invention.

6. Claim 1-3, 5, 6, 8-15, 54-57, 59, 61-68 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,876,956 (IDS) or WO 00/345 .

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US Patent 956 teaches an isolated cell population of ALDH^{br} SSC^{lo} stem cells that are CD34⁺ and CD45⁺ cells (see entire document, Abstract and column 6 in particular). Although the reference is silent about that said population of ALDH^{br} SSC^{lo} stem cells comprises at least 10% of CD105⁺ cells, said structural properties would be an inherent properties of the referenced cell composition. Since the office does not have a laboratory to test the reference cell composition, it is applicant's burden to show that the reference cell composition does not comprises at least 10% of CD105⁺ cells as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

WO' 507 teaches an isolated cell population of ALDH^{br} SSC^{lo} stem cells that are CD34⁺ and CD45⁺ cells (see entire document, pages 14 and 15 Fig.5 in particular). Although the reference is silent about that said population of ALDH^{br} SSC^{lo} stem cells comprises at least 10% of CD105⁺ cells, said structural properties would be an inherent properties of the referenced cell composition. Since the office does not have a laboratory to test the reference cell composition, it is applicant's burden to show that the reference cell composition does not comprises at least 10% of CD105⁺ cells as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Once a *prima facie* case of anticipation with a basis in fact and/or technical reasoning which reasonably supports the determination that an allegedly inherent characteristic necessarily flows from the teachings of the applied prior art is established it is applicant's burden to prove that the subject matter shown to be in the prior art does not possess the characteristics of the claimed invention. See *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Patent App. & Int. 1990); *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985); *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986) and MPEP § 2112.

Claims 8-15 and 61-68 are included because a composition is a composition irrespective of its intended use in the absence of evidence of structural difference. If the prior art structure is capable of performing the intended use, then it meets the claim. When a claim recites using an old composition or structure (e.g. ALDH^{br} SSC^{lo} stem cells) and the use is directed to a result or property of that composition or structure then the claim is anticipated. See MPEP 2112.02. Also, see *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.* 58 USPQ2d 1508 (CA FC 2001); *Ex parte Novitski* 26 USPQ 1389 (BPAI 1993); *Mehl/Biophile International Corp. V. Milgraum*, 52 USPQ2d 1303 (Fed. Cir. 1999); *Atlas Powder Co. V. IRECO*, 51 USPQ2d 1943 (Fed. Cir. 1999).

The references teaching anticipates the claimed invention.

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7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571/ 272-0735

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michail A Belyavskiy/
Primary Examiner, Art Unit 1644